Food and Drug Administration, HHS

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) Approvals. Type A medicated articles: 25 percent to No. 016592 in §510.600(c) of this chapter for use as in paragraph (d) of this section.

- (b) Special considerations. Do not use in Type B or Type C medicated feeds containing bentonite.
- (c) Related tolerances. See §556.50 of this chapter.
- (d) Conditions of use—(1) Cattle. It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for yeal.	016592
(ii) 113.5 to 11, 350; to provide 10 milli- grams per kilogram of body weight per day.	Calves: As an aid in the treatment of coc- cidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592

(2) Chickens. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5		Replacement chickens: For development of active immunity to coccidiosis.		016592

	Up to 5 weeks of age	From 5 to 8 weeks of	Over 8 weeks of age Amprolium in grams per ton	
Growing conditions	Amprolium in grams per ton	age Amprolium in grams per ton		
Severe exposure to coccidiosis	113.5	72.6–113.5	36.3–113.5	
	(0.0125%)	(0.008%–0.0125%)	(0.004%-0.0125%)	
Moderate exposure to coccidiosis	72.6–113.5	54.5–113.5	36.3-113.5	
	(0.008%-0.0125%)	(0.006%-0.0125%)	(0.004%-0.0125%)	
Slight exposure to coccidiosis	36.3-113.5	36.3-113.5	36.3-113.5	
	(0.004%-0.0125%)	(0.004%-0.0125%)	(0.004%-0.0125%)	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylenedisalicy- late 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	item (i). Bacitracin	054771
(iii) 72.6 to 113.5		Broiler chickens: For prevention of coccidiosis caused by Eimeria tenella only.		016592
(iv) 72.6 to 113.5	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis caused by Eimeria tenella only; and for in- creased rate of weight gain and improved feed efficiency.	tion; as sole source of amprolium. Bambermycins as	016592
(v) 113.5		Laying chickens: For prevention of coccidiosis.	- ''	016592

§558.58

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vi) 113.5 to 227		Laying chickens: For treatment of coccidiosis in moderate out- breaks. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously from day-old until onset of production; as the	016592
(vii) 113.5 to 227	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ra- tion; as sole source of amprolium. Bambermycins as	016592
(viii) 227		ciency. Laying chickens: For treatment of coccidiosis in severe outbreaks		016592

(3) Turkeys. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in §510.600(c) of this chapter.	016592
(ii) 113.5 to 227		Turkeys: For prevention of coccidiosis.	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) Pheasants. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159 (ii) [Reserved]		Growing pheasants: For the prevention of coccidiosis caused by Eimeria colchici, E. duodenalis, and E. phasiani.		016592

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

$\S 558.58$ Amprolium and ethopabate.

- (a) Specifications. Type A medicated articles containing:
- (1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;
- $\begin{array}{ccccc} (2)\ 25\ percent\ amprolium\ and\ 0.8\ percent\ amprolium\ and\ 0.16\ percent\ amprolium\ and\ 0.16\ percent\ amprolium\ amprolium\ and\ 0.16\ percent\ amprolium\ am$
- (b) Approvals. See No. 016592 in $\S510.600(c)$ of this chapter.
- (c) Special considerations. Do not use in Type B or Type C medicated feeds containing bentonite.
- (d) $Related\ tolerances.$ See §§ 556.50 and 556.260 of this chapter.
- (e) Conditions of use. It is used in chicken feed as follows: